REMARKS

Claims 8-10, 12, 13 and 38-41 are currently pending in this application. Applicants gratefully acknowledge that the Examiner has indicated that claims 38-41 are allowable. Claims 8-9 and 12-13 remain rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Claims 8-10 and 12-13 stand newly rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement.

Applicants have amended the claims to more clearly define and distinctly characterize Applicants' novel invention. Specifically, claim 8 was amended to recite wherein the Pellino 2 polypeptide binds to an antibody raised against an immunogen comprising an amino acid sequence of SEQ ID NO:4. Support for this amendment can be found in the specification at least at page 7, lines 26-29, where Applicants teach a Pellino 2 polypeptide that binds antibodies raised against an immunogen comprising an amino acid sequence of SEQ ID NO:4. Claim 10 was amended to incorporate the limitations of claim 8. The amendments presented herein add no new matter and do not raise new issues requiring further search. Applicants respectfully request entry and consideration of the foregoing amendments, which are intended to place this case in condition for allowance, or at least in better condition for appeal. Entry of the amendment under Rule 116 is requested.

Objections to the Specification

At page 6, section 5 of the current Office Action, the Examiner has objected to the specification, stating that pages 54 and 55 contain nucleic acid sequences that are not identified by sequence identifiers. In response, Applicants note that a Communication Under 37 C.F.R. §§ 1.821-1.825 and Preliminary Amendment mailed on April 10, 2002 amended pages 54 and 55 of the specification to include sequence identifiers, and provided paper and computer readable copies of the Sequence Listing. Accordingly, Applicants respectfully submit that this rejection is moot and request that this objection be reconsidered and withdrawn.

The Specification Provides Adequate Written Description for Claims 8-10, 12 and 13

Rejection of Claims 8, 9, 12 and 13

At page 2, section 4 of the current Office Action, claims 8, 9, 12 and 13 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Examiner is of the opinion that one skilled in the art cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. Applicants respectfully traverse this rejection based on the amended claims now presented.

Without acquiescing to the rejection, Applicants respectfully submit that claim 8 has been amended to include a particular ***physical characteristic*** wherein the claimed Pellino 2 olypeptide ***binds to an antibody raised against an immunogen comprising an amino acid sequence of SEQ ID NO:4***. Specifically, amended claim 8 and claims depending therefrom are directed to a method of detecting epithelial cancer cells in a biological sample from a mammal, the method comprising the steps of (a) providing the biological sample from the mammal, and (b) detecting an increase in copy number of a ***gene encoding a Pellino 2 polypeptide comprising at least 95% amino acid identity to SEQ ID NO:4*** in the biological sample, ***wherein the Pellino 2 polypeptide binds to an antibody raised against an immunogen comprising an amino acid sequence of SEQ ID NO:4***, thereby detecting the presence of epithelial cancer cells in the biological sample.

The first paragraph of 35 U.S.C. § 112 requires that the specification provide a written description of the claimed invention:

> [t]he specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The purpose of the written description requirement is to ensure that the specification conveys to those skilled in the art that the applicants possessed the claimed subject matter as of the filing date sought. *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 U.S.P.Q.2d (BNA) 1111,

1117 (Fed. Cir. 1991). With respect to polypeptides, the U.S. Patent and Trademark Office's Written Description Guidelines state:

> The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by . . . disclosure of relevant, **identifying characteristics**, i.e., structure or other **physical and/or chemical properties**, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus . . . .

66 Fed. Reg. 1099, 1106 (January 5, 2001), internal reference omitted, approved in *Enzo Biochem, Inc. v. Gen-Probe Incorporated*, 296 F.3d 1316, 1325, 63 U.S.P.Q.2d (BNA) 1609, 1613 (Fed. Cir. 2002) (emphasis added).

Applicants respectfully submit that the specification more than adequately describes the claimed methods with reasonable clarity to one of skill in the art. Applicants teach a combination of identifying characteristics sufficient to show that Applicants were in possession of the claimed genus. Specifically, Applicants teach a gene encoding a Pellino 2 polypeptide having a specific sequence identity (i.e., 95% amino acid identity to SEQ ID NO:4) and the physical characteristic of binding an antibody specific to an amino acid sequence comprising SEQ ID NO:4.

Applicants describe the cDNA sequence and amino acid sequence of Pellino 2 (SEQ ID NO:3 and SEQ ID NO:4, respectively), and teach that other Pellino nucleic acid and protein sequences, such as the mouse Pellino 2 mRNA sequence, have been described (specification, page 5, lines 10-23). Applicants teach that amino acid identity in the context of polypeptide sequences refers to two or more sequences or subsequences that are the same or have a specified percentage of amino acid residues or nucleotides that are the same over a specified region when compared and aligned for maximum correspondence over a comparison window or designated region as measured using a BLAST or BLAST 2.0 sequence comparison algorithm or by manual alignment and visual inspection. Thus, one of skill in the art would recognize that the specification adequately describes the Pellino 2 sequences embraced as part of the claimed method.

Applicants further describe an anti-Pellino antibody as an antibody that specifically binds a polypeptide encoded by a Pellino gene (specification, page 20, lines 31-33). Applicants teach methods of producing both monoclonal and polyclonal antibodies against Pellino 2 (specification, page 27, line 9 to page 28, line 25) using methods that were widely known to those of skill in the art at the time of filing. Applicants also teach a variety of immunoassay methods by which one of skill in the art could use the antibody to bind a Pellino 2 polypeptide (specification, page 28, line 26 to page 29, line 28). Accordingly, one of skill in the art would readily recognize the physical characteristic of binding a Pellino 2-specifc antibody.

The specification must be considered as a whole when determining whether the written description requirement is met. *In re Wright*, 866 F.2d 422, 425, 9 U.S.P.Q.2d (BNA) 1649, 1651 (Fed. Cir. 1989). The knowledge of one skilled in the art also must be considered, because the specification must "indicate[s] to persons skilled in the art that as of the [filing] date the applicant had invented what is now claimed." *All Dental Prodx LLC v. Advantage Dental Products Inc.*, 309 F.3d 774, 779, 64 U.S.P.Q.2d (BNA) 1945, 1948 (Fed. Cir. 2002). When read as a whole, taking into account the knowledge of persons skilled in the art at the filing date of the application, this specification indicates to those skilled in the art that Applicants had possession of the claimed subject matter at the time of filing. Accordingly, the Examiner is respectfully requested to reconsider and withdraw this rejection of claims 8, 9, 12 and 13 under 35 U.S.C. § 112, first paragraph.

Rejection of Claims 8-10, 12 and 13

At page 7, section 6 of the current Office Action, claims 8-10 and 12-13 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Examiner states that the limitation of a method of detecting an increase in copy number of a gene encoding a Pellino 2 polypeptide comprising at least 95% amino acid identity to SEQ ID NO:4 ***has no clear support in the*** specification and ***claims as originally filed***. The Examiner is of the opinion that the subject matter in claims 8-10, 12 and 13 broadens the scope of the invention as originally disclosed in the specification. Applicants respectfully traverse this rejection, and submit that this rejection is improper.

Applicants respectfully submit that the specification and the claims as filed provide clear support for claim 8 and claims depending therefrom. Claims as filed in the original specification are part of the disclosure and are not new matter in violation of the written description requirement (MPEP § 2163.06(III)). Claim 8, ***as filed***, recited ***a method of detecting cancer cells in a biological sample from a mammal, the method comprising the steps of***: (i) ***providing the biological sample from the mammal; and*** (ii) ***detecting an increase in copy number of a gene encoding*** a Pellino 1 polypeptide comprising at least 70% amino acid identity to SEQ ID NO:2 or ***a Pellino 2 polypeptide comprising at least 70% amino acid identity to SEQ ID NO:4 in the biological sample, thereby detecting the presence of cancer cells in the biological sample***, providing support for presently pending claim 8. The claim was subsequently amended to recite that the cancer cells were ***epithelial*** cancer cells, that the amino acid identity was ***at least 95%***, and ***to remove language regarding*** a ***Pellino 1*** polypeptide (Amendment and Response dated May 4, 2005). Accordingly, the amendments to claim 8 ***narrowed the claim***, and did not broaden it, as asserted in the Office Action.

Further, the amendments to claim 8 to recite "at least 95%" amino acid sequence identity to SEQ ID NO:4 and "epithelial" cancer cells have clear support in Applicants' specification. For example, at page 4, lines 15-18 of the specification, Applicants teach a nucleic acid encoding a Pellino 2 polypeptide, wherein the Pellino 2 polypeptide comprises at least 95% amino acid sequence identity to SEQ ID NO:4, and at page 7, lines 20-25 of the specification, Applicants teach that Pellino 2 polypeptides have an amino acid sequence that has 95% or greater amino acid sequence identity. At page 6, lines 29-30 of the specification, Applicants teach that cancer is epithelial cancer.

Thus, Applicants' specification, including the claims as filed, provides clear support for claim 8 and claims depending therefrom. Accordingly, Applicants request that this rejection of claims 8-10, 12 and 13 under 35 U.S.C. § 112, first paragraph be reconsidered and withdrawn.

Conclusion

Having addressed all outstanding issues, Applicants respectfully request entry and consideration of the foregoing amendments and reconsideration and allowance of the case. To the extent the Examiner believes that it would facilitate allowance of the case, the Examiner is requested to telephone the undersigned at the number below.

Respectfully submitted,

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